Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection
Northeast Regional Office • 205B Lowell Street, Wilmington MA 01887 • 978-694-3200

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February15, 2017

Ms. Maureen Keeler
Anika Therapeutics, Inc.
32 Wiggins Avenue
Bedford, MA 01730

BEDFORD
Transmittal No.: X273277
Application No.: NE-16-020
Class: SM50
FMF No.: 442361
AIR QUALITY PLAN APPROVAL

Dear Ms. Keeler:

The Massachusetts Department of Environmental Protection (MassDEP), Bureau of Air and Waste, has reviewed your Limited Plan Application ("Application") listed above. This Application concerns the proposed construction and operation of a fiber and film extrusion process at Anika Therapeutics, Inc. (Anika), located at 32 Wiggins Avenue in Bedford, Massachusetts (Facility). The fiber and film produced will be used for certain medical products.

This Application was submitted in accordance with 310 CMR 7.02 Plan Approval and Emission Limitations as contained in 310 CMR 7.00 "Air Pollution Control" regulations adopted by MassDEP pursuant to the authority granted by Massachusetts General Laws, Chapter 111, Section 142 A-O, Chapter 21C, Section 4 and 6, and Chapter 21E, Section 6. MassDEP's review of your Application has been limited to air pollution control regulation compliance and does not relieve you of the obligation to comply with any other regulatory requirements.

MassDEP has determined that the Application is administratively and technically complete and that the Application is in conformance with the Air Pollution Control regulations and current air pollution control engineering practice, and hereby grants this **Plan Approval** for said Application, as submitted, subject to the conditions listed below.

Please review the entire Plan Approval, as it stipulates the conditions with which the Facility owner/operator ("Permittee") must comply in order for the Facility to be operated in compliance with this Plan Approval.

1. DESCRIPTION OF FACILITY AND APPLICATION

Anika manufactures medical related products with hyaluronic acid. The Facility's total annual volatile organic compound (VOC) emissions have been less than one ton per year since the facility commenced operation in 2009.

Anika currently has no air plan approvals issued by the MassDEP, but operates under Regulation 310 CMR 7.03(25) - Biotechnology Surface Disinfection Processes and Regulation 310 CMR 7.02(6) - Aggregate Emissions.

The proposed Fiber and Film Extrusion Process consists of dissolving cross-linked hyaluronic acid in powder form (HYAFF) into the solvent dimethyl sulfoxide (DMSO). The HYAFF powder is added to the DMSO solvent slowly and mixed overnight until the powder is completely dissolved. The enclosed feed tank is equipped with a "nitrogen blanket system" to minimize VOC emissions. The HYAFF/DMSO mixture, which has a "honey-like" viscosity, is pumped from the feed tank, through a 25 micron filter to remove impurities, to the Extruder. In the Extruder area, the mixture can be either extruded as a fiber or film.

When fiber is being produced, the extruded fiber is guided through five, open vats, which contain denatured ethanol, to reduce the DMSO content in the fiber through dissolution and mass transfer operations. The initial vat has a capacity of 35 liters followed in series by four 10-liter vats. All vats are hooded to capture VOC emissions through a common manifold to a common exhaust stack. After the dissolution of DMSO from the fiber, the fiber is dried by heating it via an electric heater. Compressed air is injected to open up the fiber bundle.

For the final steps, the fine fiber is wound onto bobbins and the bobbins are soaked overnight in solvent wash baths of denatured ethanol solution to remove the remaining DMSO to less than one percent (<1%) in the fiber. The solvent wash operation is performed underneath a hood to capture VOC emissions. See Figure 1 below for the process flow diagram for the Fiber Extrusion Line.

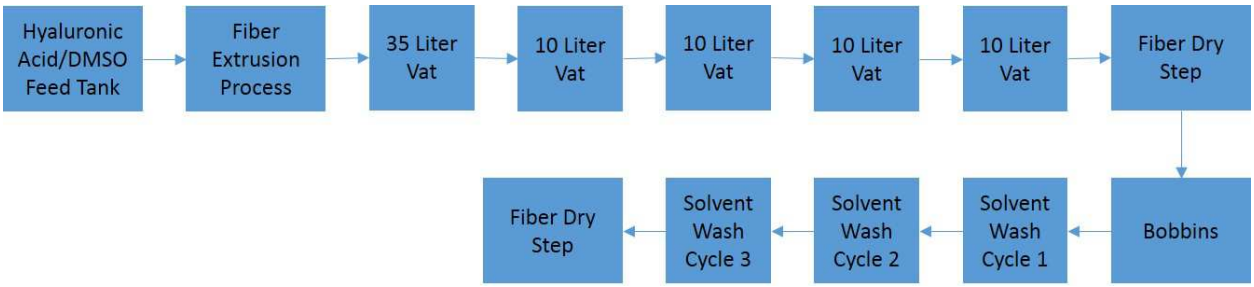

Figure 1 - Process Flow Diagram for the Fiber Extrusion Line

The Film Extrusion Line is operated similarly to the Fiber Extrusion Line, except that the vat solution consists of 80 percent denatured ethanol and 20 percent water and the initial vat is 55 liters in volume, followed by two 50 liter vats. Also, the Film Extrusion does not pass through a dryer step after exiting the vats as opposed to the Fiber Extrusion Line. After the Film Extrusion is complete, the bobbins are put in sealed plastic buckets of solvent for storage until they are washed and dried at a later date. See Figure 2 below for the process flow diagram for the Film Extrusion Line.

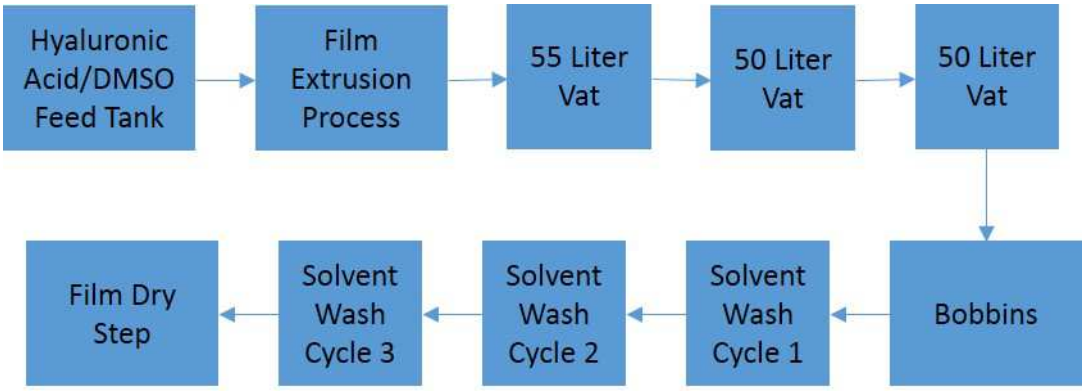

Figure 2 - Process Flow Diagram for the Film Extrusion Line

The Film Extrusion Line shares common equipment, process piping, and hoods with the Fiber Extrusion Line and therefore, the operation is limited to either the Film Line or the Fiber Line. Both lines cannot be operated simultaneously.

The Fiber and Film Extrusion Process will have two emission units, as set forth in Table 1 below. The HYAFF Extrusion Process for the Film and Fiber Lines is designated as Emission Unit No. 1 (EU1). The HYAFF Wash / Dry Process for the Film and Fiber Lines is designated as Emission Unit No. 2.

MassDEP has determined that the emission limitations listed in Table 2 below represents Best Available Control Technology (BACT) for this new fiber and film extrusion process. The Permittee shall implement Good Engineering Practices to reduce solvent emissions to maximum extent possible as listed in Table 6 below.

2. EMISSION UNIT (EU) IDENTIFICATION

Each Emission Unit (EU) identified in Table 1 is subject to and regulated by this Plan Approval:

Table 1

EU#	Description of Emission Unit	Design Capacity	Pollution Control Strategies
EU1	HYAFF Extrusion Process – - production of fiber or film that is composed of cross-linked hyaluronic acid	Fiber line produces up to 32 bobbins per batch Film line produces up to 16 bobbins per batch Fiber or Film batch requires a time duration of 56 hours to complete	Good Engineering Practices See Table 6 for Special Terms and Conditions
EU2	HYAFF Wash / Dry Process – - soaking of fiber or film bobbins in denatured ethanol to remove the DMSO	Each wash batch contains up to 8 bobbins Three wash cycles are performed for each wash batch Each wash cycle lasts for 12 hours	

Table 1 Key:
EU# = Emission Unit Number
DMSO = dimethyl sulfoxide

3. APPLICABLE REQUIREMENTS

A. OPERATIONAL, PRODUCTION and EMISSION LIMITS

The Permittee is subject to, and shall not exceed the Operational, Production, and Emission Limits as contained in Table 2:

Table 2			
EU#	**Operational Limit**	**Air Contaminant**	**Emission Limits**
EU1	Maximum extrusion batches ≤ 52 per year Fiber and Film lines cannot be operated at the same time	VOC	≤ 0.3 tons per month ≤ 2.7 tons per rolling 12 month period
EU2	Maximum solvent bath washes ≤ 208 per year	VOC	≤ 0.2 tons per month ≤ 1.5 tons per rolling 12 month period

Table 2 Key:
EU# = Emission Unit Number
VOC = volatile organic compounds
≤ = less than or equal to

B. COMPLIANCE DEMONSTRATION

The Permittee is subject to, and shall comply with, the monitoring, testing, recordkeeping, and reporting requirements as contained in Tables 3, 4, and 5 below:

Table 3	
EU#	**Monitoring and Testing Requirements**
EU1 EU2	1. The Permittee shall monitor the VOC emissions from the emission units on a monthly and annual basis.
	2. If and when MassDEP requires it, the Permittee shall conduct emission testing in accordance with EPA Reference Test Methods and regulation 310 CMR 7.13.
	3. The Permittee shall monitor all operations to ensure sufficient information is available to comply with 310 CMR 7.12 Source Registration.

Table 3 Key:
EU# = Emission Unit Number
EPA = Environmental Protection Agency
CMR = Commonwealth of Massachusetts Regulation

Table 4	
EU#	**Recordkeeping Requirements**
EU1 EU2	1. The Permittee shall maintain adequate records on-site to demonstrate compliance status with all operational, production, and emission limits contained in Table 2 above. Records shall also include the actual emissions of air contaminant(s) emitted for each calendar month and for each consecutive twelve-month period (current month plus prior eleven months). These records shall be compiled no later than the 15th day following each month. An electronic version of the MassDEP approved record keeping form, in Microsoft Excel format, can be downloaded at http://www.mass.gov/eea/agencies/massdep/air/approvals/limited-emissions-record-keeping-and-reporting.html#WorkbookforReportingOn-SiteRecordKeeping.
	2. The Permittee shall maintain records of monitoring and testing as required by Table 3.
	3. The Permittee shall maintain a copy of this Plan Approval, underlying Application and the most up-to-date Standard Operating and Maintenance Procedure (SOMP) for the Emission Units approved herein on-site.
	4. The Permittee shall maintain a record of routine maintenance activities performed on the approved EU(s). The records shall include, at a minimum, the type or a description of the maintenance performed and the date and time the work was completed.
	5. The Permittee shall maintain a record of all malfunctions affecting air contaminant emission rates on the approved EU(s). At a minimum, the records shall include: date and time the malfunction occurred; description of the malfunction; corrective actions taken; the date and time corrective actions were initiated and completed; and the date and time emission rates and monitoring equipment returned to compliant operation.
	6. The Permittee shall maintain records to ensure sufficient information is available to comply with 310 CMR 7.12 Source Registration.
	7. The Permittee shall maintain records required by this Plan Approval on-site for a minimum of five (5) years.
	8. The Permittee shall make records required by this Plan Approval available to MassDEP and EPA personnel upon request.

Table 4 Key:
EU# = Emission Unit Number
EPA = Environmental Protection Agency
CMR = Commonwealth of Massachusetts Regulation

Table 5	
EU#	**Reporting Requirements**
EU1 EU2	1. The Permittee shall notify the Northeast Regional Office of MassDEP, Bureau of Air and Waste, (BAW), Permit Chief by telephone at 978-694-3200, email at nero.air@state.ma.us, fax at 978-694-3499, as soon as possible, but no later than three (3) business days after discovery of an exceedance(s) of Table 2 requirements. A written report shall be submitted to the Permit Chief at MassDEP within ten (10) business days thereafter and shall include: identification of exceedance(s), duration of exceedance(s), reason for the exceedance(s), corrective actions taken, and action plan to prevent future exceedance(s).
	2. The Permittee shall submit to MassDEP all information required by this Plan Approval over the signature of a "Responsible Official" as defined in 310 CMR 7.00 and shall include the Certification statement as provided in 310 CMR 7.01(2)(c).
	3. The Permittee shall report every three years to MassDEP, in accordance with 310 CMR 7.12, all information as required by the Source Registration/Emission Statement Form. The Permittee shall note that any minor changes such as under 310 CMR 7.02(2)(e), 7.03 and/or 7.26, do not require Plan Approval.
	4. The Permittee shall provide a copy to MassDEP of any record required to be maintained by this Plan Approval within 30-days from MassDEP's request.
	5. The Permittee shall submit to MassDEP for approval a stack emission test protocol, at least 45 days prior to emission testing, for emission testing as defined in Table 3 'Monitoring and Testing Requirements'.
	6. The Permittee shall submit to MassDEP a final stack emission test results report, within 60 days after emission testing, for emission testing as defined in Table 3 'Monitoring and Testing Requirements'.

Table 5 Key:
EU# = Emission Unit Number
CMR = Commonwealth of Massachusetts

4. SPECIAL TERMS AND CONDITIONS

A. The Permittee shall comply with the Special Terms and Conditions as contained in Table 6 below:

Table 6	
EU#	**Special Terms and Conditions**
EU1 EU2	1. No person shall operate a facility constructed, substantially reconstructed, or altered pursuant to 310 CMR 7.02(3)(f) except in conformance with the requirements established therein and in conformance with the specific written plan approval requirements.
	2. The Permittee shall utilize best management practices, pollution prevention and limitation of hours of operating and/or raw material usage as necessary to comply with the limits specified for the emission units.
	3. The Permittee shall implement good engineering practices to reduce solvent emissions to maximum extent possible as listed below: • After finishing the fiber and film extrusion process, covers are placed over all the open solvent vats. • At the end of each extrusion day, solvent is drained from the vats to prevent further evaporative emissions. • The containers, where the fiber and film products are washed, are equipped with lids to reduce emissions. • All other process tanks and piping are closed systems. • All closed process tanks are equipped with a nitrogen blanket system to prevent emissions. • The hose fittings that are used to charge the DMSO into the portable tanks are drip-free fittings.

Table 6 Key:
EU# = Emission Unit Number
CMR = Commonwealth of Massachusetts

B. The Permittee shall install and use an exhaust stack, as required in Table 7, on each Emission Unit that is consistent with good air pollution control engineering practice and that discharges so as to not cause or contribute to a condition of air pollution. Each exhaust stack shall be configured to discharge the gases vertically and shall not be equipped with any part or device that restricts the vertical exhaust flow of the emitted gases, including but not limited to rain protection devices known as “shanty caps” and “egg beaters.”

C. The Permittee shall install and utilize an exhaust stack with the following parameters, as contained in Table 7 below, for the Emission Units that are regulated by this Plan Approval:

Table 7				
EU#	**Stack Height Above Ground (feet)**	**Stack Inside Exit Dimensions (feet)**	**Stack Gas Exit Velocity Range (feet per second)**	**Stack Gas Exit Temperature Range (^{o}F)**
EU1 EU2	55*	3.167	45 to 55	65 to 75

Table 7 Key:
EU# = Emission Unit Number
^{o}F = Degree Fahrenheit

Table 7 Note:
*The stack is 18 feet above the roof.

5. GENERAL CONDITIONS

The Permittee is subject to, and shall comply with, the following general conditions:

A. Pursuant to 310 CMR 7.01, 7.02, 7.09 and 7.10, should any nuisance condition(s), including but not limited to smoke, dust, odor or noise, occur as the result of the operation of the Facility, then the Permittee shall immediately take appropriate steps including shutdown, if necessary, to abate said nuisance condition(s).

B. If asbestos remediation/removal will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that all removal/remediation of asbestos shall be done in accordance with 310 CMR 7.15 in its entirety and 310 CMR 4.00.

C. If construction or demolition of an industrial, commercial or institutional building will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that said construction or demolition shall be done in accordance with 310 CMR 7.09(2) and 310 CMR 4.00.

D. Pursuant to 310 CMR 7.01(2)(b) and 7.02(7)(b), the Permittee shall allow MassDEP and / or USEPA personnel access to the Facility, buildings, and all pertinent records for the purpose of making inspections and surveys, collecting samples, obtaining data, and reviewing records.

E. This Plan Approval does not negate the responsibility of the Permittee to comply with any other applicable Federal, State, or local regulations now or in the future.

F. Should there be any differences between the Application and this Plan Approval, the Plan Approval shall govern.

G. Pursuant to 310 CMR 7.02(3)(k), MassDEP may revoke this Plan Approval if the construction work is not commenced within two years from the date of issuance of this Plan Approval, or if the construction work is suspended for one year or more.

H. This Plan Approval may be suspended, modified, or revoked by MassDEP if MassDEP determines that any condition or part of this Plan Approval is being violated.

I. This Plan Approval may be modified or amended when in the opinion of MassDEP such is necessary or appropriate to clarify the Plan Approval conditions or after consideration of a written request by the Permittee to amend the Plan Approval conditions.

J. Pursuant to 310 CMR 7.01(3) and 7.02(3)(f), the Permittee shall comply with all conditions contained in this Plan Approval. Should there be any differences between provisions contained in the General Conditions and provisions contained elsewhere in the Plan Approval, the latter shall govern.

6. MASSACHUSETTS ENVIRONMENTAL POLICY ACT

MassDEP has determined that the filing of an Environmental Notification Form (ENF) with the Secretary of Energy & Environmental Affairs, for air quality control purposes, was not required prior to this action by MassDEP. Notwithstanding this determination, the Massachusetts Environmental Policy Act (MEPA) and 301 CMR 11.00, Section 11.04, provide certain "Fail-Safe Provisions," which allow the Secretary to require the filing of an ENF and/or an Environmental Impact Report (EIR) at a later time.

7. APPEAL PROCESS

This Plan Approval is an action of MassDEP. If you are aggrieved by this action, you may request an adjudicatory hearing. A request for a hearing must be made in writing and postmarked within twenty-one (21) days of the date of issuance of this Plan Approval.

Under 310 CMR 1.01(6)(b), the request must state clearly and concisely the facts, which are the grounds for the request, and the relief sought. Additionally, the request must state why the Plan Approval is not consistent with applicable laws and regulations.

The hearing request along with a valid check payable to the Commonwealth of Massachusetts in the amount of one hundred dollars ($100.00) must be mailed to:

Commonwealth of Massachusetts
Department of Environmental Protection
P.O. Box 4062
Boston, MA 02211

This request will be dismissed if the filing fee is not paid, unless the appellant is exempt or granted a waiver as described below. The filing fee is not required if the appellant is a city or town (or municipal agency), county, or district of the Commonwealth of Massachusetts, or a municipal housing authority.

MassDEP may waive the adjudicatory hearing-filing fee for a person who shows that paying the fee will create an undue financial hardship. A person seeking a waiver must file, together with the hearing request as provided above, an affidavit setting forth the facts believed to support the claim of undue financial hardship.

Should you have any questions or comments regarding this letter, please feel free to contact Joseph Su at (978) 694-3200 or joseph.su@state.ma.us.

Sincerely,

_____
Susan Ruch
Acting Permit Chief and
Deputy Regional Director
Bureau of Air and Waste

_____
Joseph Su
Environmental Engineer

cc: Bedford Town Hall, 10 Mudge Way, Bedford, MA 01730, Attn: Board of Health Director
Bedford Fire Department, 55 Great Road, Bedford, MA 01730, Attn: Fire Department Chief
Amec Foster Wheeler, 271 Mill Road – 3rd floor, Chelmsford, MA 01824, Attn: Mr. Andy Roland
MassDEP - Martha Bolis

ecc: MassDEP – NERO: Edward Braczyk, Martha Bolis
MassDEP – Boston: Yi Tian